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PATENT
Customer No. 22,852
Attorney Docket No. **07883.0046**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
Peter BOEKSTEGERS et al.	)	Group Art Unit: 3764
Application No.: 09/917,655	)	Examiner: Q. Thanh
Filed: July 31, 2001	)	
For: MYOCARDIAL STENTS AND RELATED METHODS OF PROVIDING DIRECT BLOOD FLOW FROM A HEART CHAMBER TO A CORONARY VESSEL	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO OFFICE ACTION DATED AUGUST 7, 2003 AND REQUEST FOR RECONSIDERATION

In the Office Action dated August 7, 2003, all of the pending claims 1, 3-8, 10-22, and 24-35 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,406,488 to Tweden et al. ("Tweden") in view of U.S. Patent No. 6,409,697 to Eno et al. ("Eno").

As will be explained in more detail below, the Section 103 rejection of the pending claims based on the combination of Tweden and Eno should be withdrawn because a *prima facie* case of obviousness has not been set forth.

To establish a *prima facie* case of obviousness, three basic criteria must be satisfied. First, there must be some suggestion or motivation, either in the references

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themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or to combine references. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim elements. See M.P.E.P. § 2143. Moreover, if the proposed modification either renders the reference being modified unsatisfactory for its intended purpose or changes the reference's principle of operation, there is not suggestion or motivation to make the proposed modification. See M.P.E.P. § 2143.01

In the present case, at least the first prong of this test has not been satisfied. That is, there is no suggestion or motivation to combine Tweden and Eno in the manner set forth in the Office Action because Tweden explicitly teaches against the hypothetical modification proposed by the Examiner and to make such a modification would render Tweden unsatisfactory for its intended purpose and destroy the explicitly taught principles of operation of Tweden. Thus, one having ordinary skill in the art would not have been motivated to modify Tweden with Eno in the manner set forth in the rejection.

Tweden teaches a transmyocardial implant for establishing a blood flow path through a myocardium between a heart chamber and a lumen of a coronary vessel. (See Abstract.) Referring to Figs. 1-3, Tweden further discloses the implant as a conduit 10 in the form of an L-shaped tube. (Col. 2, lines 47-48.) In particular, Tweden discloses that the conduit 10 has a coronary portion 12 sized to be received within the lumen 80 of a coronary artery 82 distal to an obstruction 81. (Col. 2, lines 56-58.) Tweden teaches that the longitudinal axis of the coronary portion 12 is aligned with the axis of the lumen 80. (Col. 3, lines 4-6.) The conduit 10 further includes a myocardial portion 14 extending at a right angle to the axis of the coronary portion 12. (Col. 2, lines

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59-61.) Tweden further discloses that the coronary portion 12 has a first opening 16 and the myocardial portion 14 has a second opening 18. In this way, blood flows through the implant 10 between the left ventricle 83 and the lumen 80 of the coronary artery 82. Tweden explicitly discloses that the blood flow is in an axial direction out of the coronary portion opening 16 such that it is parallel with the axis of the lumen 80 of the coronary artery 82. (Col. 2, line 64 - col. 3, line 3.)

At col. 3, lines 56-64, Tweden emphasizes that providing the conduit 10 with a flexible transition portion 13 between the myocardial portion 14 and the coronary portion 12 so as to permit relative articulation between the two portions "***ensure[s]*** the coronary portion is axially aligned with the lumen 80 [of the coronary artery 82]." (Emphasis added.) Tweden explains, however, that absent articulation, such axial alignment is achieved by "accurately controlling the position of the myocardial portion 14 such that the coronary portion 12 is axially aligned with the lumen 80 following implantation." Thus, the implant disclosed by Tweden is an implant having an "L-shaped" structure with a myocardial portion and a coronary portion disposed at right angles to each other. Tweden emphasizes that the implant has a coronary portion aligned along the axis of the coronary vessel. There is no embodiment of an implant disclosed or otherwise suggested in Tweden that lacks such a coronary portion that is axially aligned with the lumen of the coronary vessel in which it is placed. Indeed, the emphasis in Tweden on the coronary portion and its alignment with the lumen of the coronary artery is a teaching against an implant without such a coronary portion disposed at an angle to the myocardial portion.

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Eno discloses a transmyocardial implant with a forward flow bias that establishes a blood flow path through a heart wall between a heart chamber and a lumen of a coronary vessel. As shown in Fig. 1 and 1A, Eno discloses the implant being in the form of a straight, elongate, and generally cylindrical conduit 11. (Col. 2, lines 22-24.) Eno discloses that the conduit 11 is formed of a rigid biocompatible material. (Col. 2, lines 24-25.) Eno further discloses that the conduit 11 has a first open end 12 sized to be received in the lumen 100 of a coronary artery 102 and a second open end 14 which protrudes into the left ventricle 106. (Col. 2, lines 43-54.)

In the Section 103 rejection based on Tweden and Eno, the Examiner acknowledges that Tweden's stent "is an L-shaped tube and is not substantially straight." (Office Action, page 3.) The Examiner then relies on Eno's teaching of a substantially straight myocardial conduit 11 and asserts it would have been obvious to one of ordinary skill in the art "to substitute the L-shaped stent of Tweden with the straight stent of Eno, as suggested and taught by Eno, since both are well known in the art as equivalent means for medical implant stent." (Office Action, page 3.) The Examiner further asserts that to make this proposed modification of Tweden also would be "an obvious matter of design choice" "since applicant has not disclosed that having a substantially straight stent solves any stated problem or is for any particular purpose and it appears that the device would perform equally well with either designs."

The Examiner's assertions regarding the obviousness of modifying Tweden's L-shaped conduit such that it is substantially straight, whether relying on the teachings of Eno or some alleged "design choice," are clearly unsupported in view of Tweden's explicit teachings to use implants having a coronary portion and therefore not to use a

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straight implant, as explained above. Tweden explicitly teaches the use of an L-shaped conduit and the importance of "ensur[ing]" that the coronary portion 12 of the conduit 11 is axially aligned with the lumen of the coronary artery. To modify the L-shaped conduit having a coronary portion that is axially aligned with the lumen of the coronary artery of Tweden in the manner suggested in the Office Action, *i.e.,* by taking away the coronary portion and leaving only the substantially straight myocardial portion, would destroy the operation and advantages that are explicitly taught and emphasized by Tweden. For instance, the purposes of the implant structure disclosed by Tweden, and the various advantages associated with that structure, include permitting a flow of blood from the left ventricle through the heart wall and along the axial direction of the lumen of the coronary artery, which the substantially straight myocardial implant of Eno would not achieve. By making this hypothetical combination, the Examiner appears to simply pick individual pieces from the prior art references and attempts to combine them without having any motivation whatsoever to do so. Under the provisions of M.P.E.P. § 2143.01, such a proposed modification resulting in a change in the principle of operation of and rendering unsatisfactory for its intended use the prior art being modified does not support a *prima facie* case of obviousness.

Regarding the Examiner's assertion at page 3 of the Office Action that "Eno also suggests that while the tube 11 is preferably straight, the tube 11 could be bent so that the direction of blood from end 12 is not perpendicular to the arterial blood flow direction A," combining this teaching by Eno of a bent tube with Tweden would only result in a non-straight, or bent, implant similar to that taught by Tweden and which is not set forth in Applicants' claims.

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Additionally, the various assertions regarding obvious design choice and the absence of "a teaching as to criticality that the stent is substantially straight" in the Office Action at page 3, amount to nothing more than conclusory assertions and do not fulfill or remove the Examiner's obligation to provide motivation for the modification of Tweden forming the basis of the obviousness rejection of the pending claims.

Based on at least these reasons, one of ordinary skill in the art would not have been motivated to modify Tweden with Eno or any other alleged design choice modification, and indeed would have been inclined not to make such a combination, in the manner suggested in the Office Action. Accordingly, Applicants respectfully request the withdrawal of the Section 103 rejection of the pending claims.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

Claims 3-8, 10-15, 18-22, 24-28, and 30-35 depend from one of independent claims 1, 16, 17, and 29 and are therefore allowable for at least the same reasons each of those claims is allowable. In addition, at least some of the dependent claims recite unique combinations that are neither taught nor suggested by the cited art, and therefore also are separately patentable.

Applicants request the withdrawal of the outstanding claim rejections and the timely allowance of claims 1, 3-8, 10-22, and 24-35.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: November 6, 2003

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